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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,333	07/13/2005	John Gary Montana	GJE-7230	7930
<div>23557 7590 08/29/2007</div> <div>SALIWANCHIK LLOYD & SALIWANCHIK</div> <div>A PROFESSIONAL ASSOCIATION</div> <div>PO BOX 142950</div> <div>GAINESVILLE, FL 32614-2950</div>				
			EXAMINER	
			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			08/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,333

Applicant(s)

MONTANA ET AL.

Examiner

Taofiq A. Solola

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-9 and 11-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: ____ |

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Claims 1-9, 11-21 are pending in this application.

Claim 10 is cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-21, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. The claims are drawn to method of treating or preventing disorders associated with GnRH, such as cancers, leukemia, fertility disorders, HIV and AIDs. The specification fails to provide conclusive evidence that the instant compounds could be used for treating or prevent all diseases associated with GnRH or all cancers. There is no assay in the specification confirming the activity of any of the instant compounds as antagonist of GnRH.

Claims 12-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for using the instant compounds for the treatment and/or prevention of disorders associated with GnRH, such as cancers, leukemia, fertility disorders, HIV and AIDs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

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"In the context of determining whether sufficient "utility as a drug, medicant, and the like in human therapy" has been alleged, It is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [compounds and the utilities] as obviously correct." *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see 340 F.2d 974, 977-78 (CCPA 1965).

"A specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), *Id.* at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel*, 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); *Bowen*, 492 F.2d 859 (CCPA 1974); *Hawkins*, 486 F.2d 569, 576 (CCPA 1973).

Where there is "no indication that one skilled in the art would accept without question [the instant compounds and method of use] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement." *In re Rasmusson*, 75 USPQ2d 1297 (CAFC 2005). The claimed utility is not enable without undue experimentation for the following reasons:

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

"The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the

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invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. The specification states:

Compounds of the invention may act as GnRH antagonists. Accordingly, another aspect of the invention is the use of a compound of formula (I) for the manufacture of a medicament for the treatment or prevention of a disease or condition associated with GnRH. The compounds may have utility in the treatment or prevention of a fertility disorder, Alzheimer's disease, HIV infection, AIDS, fibrosis, endometriosis, uterine fibroids, uterine leiomyoma or cancer (e.g. leukemia).

The above statement is speculative at best and therefore, cannot be the basis of support for the instantly claimed utilities.

There is no evidence that the instant compounds would treat and/or prevent all disorders associated with GnRH or all categories of cancers namely: carcinoma, sarcoma myeloma, leukemia, lymphoma and mixed types. No assay is described in the specification.

The "fact that [the] art of cancer chemotherapy is highly unpredictable places on drug patent applicants to provide basis for believing speculative statements placed in the specification as positive assertion are true, and failing such, ignorance of PTO in not being able to provide scientific reason why assertion is not sound is not justification for permitting assertion to be made, where those of ordinary skill in the art would not accept assertions as believable without some data or other evidence to support it." *In re Hozumi*, 226 USPQ 353, (ComrPats, 1985).

Even though "the state of cancer treatment has advanced remarkably, decisional law would seem to indicate that the [instantly claimed] utility is sufficiently unusual to justify an

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examiner's requiring substantial evidence, which may be in the form of animal tests." *Ex parte Krepelka, et al.*, 231 USPQ 746 (BdPatApp&Int, 1986).

According to Anderson et al., WO 2000/0202358, antagonist of human GnRH are suitable for treating reproductive disorders and steroid hormone-dependent tumors as well as for regulating fertility where suppression of GnRH is indicated. This statement does not support treating and preventing all disorders associated with GnRH, all forms of cancers or all the instantly claimed utilities.

MPEP 2164.01(a) states, "[a] conclusion of lack of enablement means that, based on the evidence regarding any of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. The purpose of 35 USC 112 is to obviate the need for this type of experimentation. *In re Borkowski*, 164 USPQ 642 (CCPA, 1970). See also, *Univ. of Rochester v. G.D. Searle & Co*, 68 USPQ2d 1424 (DC WNY, 2003). By deleting the claims the rejection would be overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., WO 2000/020358, in view of King, Med Chem: Principle and Practice (1994), p. 206-209.

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Applicant claims compounds of formula I, their compositions and methods of use.

Determination of the scope and content of the prior art (MPEP 2141.01)

Anderson et al., teach specific species compounds, their compositions and the same methods of use. See compounds in the attached abstract, which are exemplifications of the numerous species by Anderson et al.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Anderson et al., is that in compounds of Anderson et al., applicant replaced >C< with >Si< in the naphthyl ring and -O- with -S- or -N- in the furan ring.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, King teaches that replacement of >C< with >Si< or -O- with -S- or -N- in a ring is expected to produce compounds having similar biological activity (bioisosterism). See page 208, bivalent and tetravalent equivalents. See also, *Ex parte Engelhardt*, 208 USPQ 343 (Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir. 1986). Therefore, the instant invention is prima facie obvious from the teachings of Anderson et al., and King. One of ordinary skill in the art would have known to replace >C< with >Si< or -O- with -S- or -N- in a ring at the time the instant invention was made. The motivation is from knowing that >C< and >Si<; or -O-, -S- and -N- are bioisosteres equivalents.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Taofiq Solola', with a stylized flourish at the end.

TAOFIQ SOLOLA
PRIMARY EXAMINER

Group 1625

August 10, 2007